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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/517,038

08/25/2005

Damijan Miklavcic

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EXAMINER

HOBBS, MICHAEL L

ART UNIT

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1797

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,038	Applicant(s) MIKLAVCIC ET AL.	
	Examiner MICHAEL HOBBS	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/07/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis for signal generating means on line 2 of claim 1 or controlling means in line 10 of claim 1 and line 2 of claim 2, there is no antecedent basis for the "timing means" within the specification. Also, there is a lack of antecedent basis for hazard detecting means on line 2 of claim 4. Furthermore, there is no antecedent basis for the limitation on line 2 of claim 12 to "extract molecules from the living cells".
3. Appropriate corrective action is required.

Claim Objections

4. Claim 1 is objected to because of the following informalities: on line 7 of claim 1, applicant states that the "ration (GT) of current (ie)" which is interpreted as ratio instead of "ration" and is assumed to be a minor spelling error.

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5. Claim 4 is objected to because of the following informalities: on line 6 of claim 4, applicant states that the "calculated instaneous gradient" which is interpreted interpreted as instantaneous instead of "instaneous " and is assumed to be a minor spelling error.
6. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. The claims are drafted using "means for" language and therefore it is presumed that the applicant wishes that the scope of the claims to be determined in accordance with 35 U.S.C. 112, sixth paragraph. In order to interpret the claims in accordance with 35 U.S.C. 112, sixth paragraph, the specification must clearly describe what structural elements constitute the "means for" performing the claimed function. The specification fails to comply with this requirement.
10. Claims 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claim 12 provides for the use of "extract[ing] molecules from living cells", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

13. Claim 13 provides for the use of "introduce[ing] molecules into living cells", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

14. Claim 14 provides for the use of "the device as claimed in claim 13"; but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

15. Claims 12, 13 and 14 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App.

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1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 1-11, 13 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Miklavcic et al. (WO 01/815333 A1) (will be referred to as Miklavcic).

19. Miklavcic discloses an electroporation device that for claim 1 includes a signal generator such as a voltage pulse generator (generator 3) where that signal is supplied to a substrate (tissue 35) by means of a pair of electrodes (electrode 5; page 3 lines 23-28). Miklavcic also includes a measuring, monitoring and calculating means such as a microprocessor (CPU 12) with RAM (memory 14) and a measuring means ((7, 10, 100) and a calculating means (120). The measuring, monitoring and calculating means of

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Miklavcic is fully capable of monitoring the ratio of the current (I_e) and the voltage (V_p) sent by the signal generator (generator 3; page 4 lines 1-4; page 12 lines 11-19).

Furthermore, the ratio GT is being interpreted as the capacitance of the substrate where $R=V/I$ and $1/R=C=GT=I/V$. Since Miklavcic discloses measuring the impedance of the substrate, it is well within the skills of one of ordinary skill in the art to measure GT or the capacitance of the substrate. Also, the microprocessor of Miklavcic is fully capable of applying the signal to the electrodes based on an initial waveform.

20. With regards to claim 2, the microprocessor (CPU 12) of Miklavcic is fully capable of applying a stimulating signal for a pre-determined time period based on an initial analysis of the waveform and for claim 3 the microprocessor (CPU 12) is fully capable of calculating the slope of the waveform curve, C_{GT} . Furthermore, for claim 4, the calculating means (120) is fully capable of determining if tissue damage (hazard) will occur. While not specifying a "comparing means", the microprocessor (CPU 12) and calculating means (120) are fully capable of comparing the instantaneous gradient dG to a reference. Furthermore, Miklavcic discloses measuring the impedance of the substrate and comparing that to a threshold or reference (see page 5 lines 15-19) and is therefore within the skills of one of ordinary skill in the art.

21. With regards to claim 5, Miklavcic further discloses an application means (130) which supply the electrodes with an electric signal and the application means is also fully capable of shutting off the voltage to prevent deterioration of the cells. For claim 6, the microprocessor (CPU 12) is fully capable of determining the average variation of ΔG . Furthermore, for claims 7 and 8, the microprocessor is fully capable of comparing

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the ratios of ΔG and determining if the voltage sent to the cells needs to be increased, maintained or shut off. Furthermore, it is within the skills of one of ordinary skill in the art to adjust the ratio of the current to voltage based on the data sent to the processor by the measuring means (7, 10, 100; see also page 5 lines 20-25). Also for claim 9, the microprocessor is fully capable of increasing the voltage pulses based on the impedance value from the cells (page 10 lines 10-14). Furthermore, the processor (CPU 12) is fully capable of detecting a portion of the curve or waveform of the pulse sent to the cells. Also, for claim 11, Miklavcic discloses three operating conditions that generate further pulses to the substrate (35) based on a predetermined time and the instantaneous impedance between the electrodes (page. 8 lines 4-10). With regards to claims 13 and 14, Miklavcic discloses the step of injection into a living cell a molecule such as a DNA molecule, oligonucleotide, a protein, or peptide, a cytotoxic agent or penicillin (page. 9 lines 4-26).

22. Therefore, Miklavcic meets the limitations of claims 1-11, 13 and 14.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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24. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

25. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

26. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Miklavcic et al. (WO 01/815333 A1) (will be referred to as Miklavcic) in view of Dunn et al. (US 6,653,091 B1) (will be referred to as Dunn).

27. Miklavcic is silent regarding the extraction of molecules from a living cell.

28. Dunn discloses an electroporation device that can extract an analyte from a living cell. With regards to claim 12, Dunn discloses extracting a glucose molecule from a cell (col. 14 lines 30-32). The extracted glucose determines the blood glucose level of the patient. Therefore, it would be obvious to one of ordinary skill in the art to employ the

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electrochemical extraction as suggested by Dunn in order to extract a target molecule from the cells of Miklavcic. The suggestion for doing so at the time would have been in order to facilitate the detection of the analyte within the collection reservoirs (col. 14 liens 26-28).

Conclusion

29. Claims 1-14 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/
Primary Examiner, Art Unit 1797

/M.H./
MLH